Regulation of Stem Cell and Regenerative Science

REGULATION OF STEM CELL AND REGENERATIVE SCIENCE: STAKEHOLDER OPINIONS, PLURALITY AND ACTOR SPACE IN THE ARGENTINE SOCIAL/SCIENCE SETTING

Shawn H.E. Harmon*

Cite as: S. Harmon, "Regulation of Stem Cell and Regenerative Science: Stakeholder Opinions, Plurality and Actor Space in the Argentine Social/Science Setting" (2010) 2(1) Law, Innovation and Technology 95-114

Abstract: This paper articulates in broad terms a model bioscience environment and its primary constituent parts, which include bioscience policy and regulation, technology deployment and stakeholder engagement, and science innovation systems. Then, having reference to empirical data generated by the GET: Social Values Project, it offers an explanation of how the Argentine environment departs from that ideal model. Finally, focusing on one constituent part of the environment – the policy and regulatory space – it reports on Argentine stakeholder opinions and desires and what these mean for the potential to adopt facilitative regulation in Argentina. It concludes that the Argentine scientific environment is sub-optimal and poorly equipped to deal effectively and positively with the plurality of ideas that people have for both the trajectory of science and its regulation. It ends with a call for further research which broadens the evidence base and thereby facilitates the improvement of the social/science environment and its constituent parts.

Keywords: biotechnology – stem cells – research – regulation – legislation – ethics – plurality – innovation – actor networks

INTRODUCTION

There has been a lot of noise from Argentina, both before and since the 2007 formation of the Ministry of Science, Technology and Innovative Production (MOST), about the importance of science both generally and developmentally, and there has been some interest from Argentine policymakers and regulators in stem cells as a means of building competitiveness in the biosciences,[1] where Argentina has enjoyed historical success.[2] Recent activities have included the following:

---

* Research Fellow, INNOGEN, ESRC Centre for Social and Economic Research on Innovation in Genomics, University of Edinburgh, and SCRIPT, AHRC Centre for Research on Intellectual Property and Technology Law, University of Edinburgh; Member of the Nova Scotia Bar; BA, Saint Mary's University (1993); LLB, University of New Brunswick (1996); LLM, University of Edinburgh (2004). The author would like to acknowledge and thank the generous support of the ESRC to this research.

1 See P. Smaglik, "Argentina's Pivotal Moment" (2008) 451 Nature 494-496.

2 Argentina has had a number of Nobel Laureates in the biosciences, including Bernardo Houssay, Luis Leloir, and César Milstein, and some elements of Argentine research have been described as close to the 'frontier' of international knowledge: see P. Kreimer and M. Lugones, "Rowing Against the Tide: Emergence and Consolidation of Molecular Biology in Argentina, 1960-90" (2002) 7 Science, Technology and Society 285-311.

- promotion of international networks and increasing public funds available to sci-tech and bioscience development;[3]

- formation of the Advisory Commission on Regenerative Medicine and Cellular Therapies by the MOST in 2008;

- issuance of governmental press releases calling attention to the benefits of biosciences like stem cell research;[4] and

- signing of international agreements with specified groups to promote scientific innovation and international cooperation.[5]

Despite these efforts, it remains to be seen whether Argentina can effectively build on its achievements and existing strengths and realise international bioscience competitiveness in anything other than a peripheral manner.[6]

This paper considers one element of the means by which bioscience, and more particularly stem cell and regenerative medicine research, can be facilitated and enhanced in Argentina, namely the bioscience environment and its constituent parts. In doing so, it draws on evidence generated by a project entitled 'Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina' (GET: Social Values).[7] After outlining the methodology adopted for the empirical research, the paper articulates in broad terms a model for a positive bioscience environment and its primary constituent parts which can be distilled from this and other evidence. Then, having reference to the empirical evidence, it offers an explanation of how the Argentine environment departs from that model. Finally, focusing on one constituent part of the environment – the policy and regulatory space – it reports on Argentine stakeholder opinions and desires and what they mean for the potential to adopt facilitative regulation in Argentina.

METHODOLOGY

The GET: Social Values Project was designed with the intention of gathering qualitative data around key issues of bioscience, and in particular stem cell research governance, in Argentina, the objective being to discover stakeholder values relevant

---

[3] J. Niosi and S. Reid, "Biotechnology and Nanotechnology: Science-Based Enabling Technologies as Windows of Opportunity for LCDs" (2007) 35 World Development 426-438, and E. Trigo and E. Cap, "Ten Years of Genetically Modified Crops in Argentine Agriculture" (2006), available at http://www.inta.gov.ar/ies/docs/otrosdoc/resyabst/ten_years.htm [accessed 4 August 2009].

[4] See Argentine Science and Technology Commission, National Congress, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009], and Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies, Ministry of Science, Technology and Productive Innovation, available at http://www.mincyt.gov.ar/index.php?contenido=comision_celulas_madre1/ [accessed 3 August 2009].

[5] N. Bar, "El Rating de la Ciencia", *La Nación*, 13 May 2009, available at http://rcdtx.lanacion.com.ar/nota.asp?nota_id=1127536 [accessed 3 August 2009].

[6] For more on the traditionally peripheral nature of Argentina's scientific endeavours, see P. Kreimer and M. Lugones, supra, note 2.

[7] Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina (ESRC Responsive Grant Award No. RES-000-22-2678). For more on the Project, see the official Project website at http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/index.asp, or go to ESRC Society Today at http://www.esrcsocietytoday.ac.uk/.

to, and objectives for, this science and its governance. While the data generated by the 22 semi-structured interviews cannot be said to represent the Argentine view – the subject sample was too narrow and too small for such claims – it captures important qualitative evidence of the views of key stakeholders in the field. Moreover, it has been welcomed by relevant stakeholders as an early and important first step in examining the social context of bioscience (and stem cell) innovation in Argentina. It has enjoyed the support of the Argentine policymaking community, which has facilitated access to some of those actors most interested in, and relevant to, stem cell research governance.

Prior to commencement, the GET: Social Values Project was subject to initial institutional ethics review and then funding body ethics evaluation. Research participants were chosen from the medical, scientific, academic, policy, legislative and regulatory communities.[8] As the project was never intended to be a public engagement mechanism, the opinions of the broader general public were not solicited. Rather, those originally viewed as most likely to influence the nature and content of bioscience and stem cell regulation in Argentina were targeted (ie: Argentine science policy elites), for, it was felt, only by targeting those most engaged in the pre-legislative process could we measure the existence of functional connections between values and objectives, on the one hand, and legal outputs (when they emerge), on the other.

Following preliminary desktop research on the regulatory setting,[9] semi-structured interviews lasting 50 to 90 minutes were conducted. Each interview was, with permission, recorded. Open-ended questions and an informal interview schedule were used to encourage participants to speak in their own words about their experiences, observations, opinions, and desires. In some cases, more structured information was obtained through questionnaires. Transcription of the interviews was performed within Innogen (one the Principal Investigator's host institutes) and that work was subject to a signed Confidentiality Agreement. Anonymised transcripts were shared between the Principal Investigator (in Edinburgh) and the Collaborating Investigator (in Buenos Aires) and have been retained for archiving. Every line of transcription and interviewer notes was coded and analysed for emergent themes, and sections relating to those themes were grouped together. The whole assessment was refined through an iterative process, thus enabling different perspectives and interpretations to be incorporated. The quotes used in the present paper were chosen as reflective of widely canvassed themes, and are deployed to make particular points or support particular claims or recommendations.

ANALYSIS

I. DOING 'GOOD' SCIENCE: THE SOCIAL/SCIENCE ENVIRONMENT AND ACTOR SPACE

[8] The investigators interviewed at least one respondent, but often multiple respondents, from each of the following categories: cabinet level politician; national congressional member; national regulatory agency member; national advisory committee member; medical clinician, medical researcher, basic scientist, ethicist, academic lawyer.

[9] See S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) 8(2) Developing World Bioethics 138-150.

It is clear from actor-network scholarship,[10] and (related) innovation systems scholarship,[11] that the advancement of science is not realised by any linear or straightforward process; it involves a plethora of interdependent public and private actors and evolving social networks interacting with each other and with existing technologies, and it equally relies on other factors such as laws, rules, norms and routines, all feeding essential information into the innovation cycle which, when operating properly, generates new knowledge and better products and practices. Bearing this in mind, I suggest that the 'best science'[12] is most likely to emerge from a dynamic, inclusive and positive/facilitative value-conscious social/science environment. Such an environment is characterised by the ability of diverse stakeholders to (safely) advance their ideas of the good life and the just society, and their (reasoned) notions of morally defensible science. A healthy social/science environment is richly populated by 'actors', 'artefacts' and 'nodes', and it is absolutely reliant on the open exchange of ideas and therefore the co-production (and reproduction) of actors, nodes and artefacts, and, ultimately, of scientific knowledge and useful products and processes.

In this model, 'actors' are individuals, institutions, organisations and social networks; a diverse collection of interested people and entities with overlapping and shifting allegiances *to* actor groups and alliances *with* actor groups. Actors generate and release, and, in turn, receive information and ideas, thereby helping to shape one another and giving content to both the subject matter (here bioscience) and the environment.

'Artefacts' are vital structures/scaffolds which link the specific environment to other external or related environments, and which, more importantly, serve an ongoing shaping/influencing and/or monitoring function within the subject environment. They are designed by humans and, in turn, influence the action and imagination of humans through their interaction with each other and with the actors (ie: they inscribe their characteristics on the human psyche but are similarly influenced and continually reconstituted by human actors). Artefacts can include (1) national (or regional) science policies, including funding policies, and science regulation and related legislation, (2) formal and informal national, regional or sectoral innovation systems (which implicates the former but also includes industry actors, objects, and shapers, and active international collaborations), and (3) existing technologies and technical practices. Ultimately, artefacts contribute to the generation of science innovation and to the translation of that innovation into socially useful products and practices, each exerting their own influence and limitations. When the social/science environment is healthy, its constituent elements reproduce, mutually

---

[10] See P. Gao, "Using Actor-Network Theory to Analyse Strategy Formulation" (2005) 15 Information Systems J 255-275, S. Fox, "Communities of Practice, Foucault and Actor-Network Theory" (2000) 37 J Management Studies 853-867, A. Prout, "Actor-Network Theory, Technology and Medical Sociology: An Illustrative Analysis of the Metered Dose Inhaler" (1996) 18 Sociology of Health & Illness 198-219, and more.

[11] See C. Edquist (ed.), *Systems of Innovation: Technologies, Institutions and Organisations* (London: Routledge, 1997), J. Niosi, "National Systems of Innovations are 'X-Efficient' (and 'X-Effective'): Why Some are Slow Learners" (2002) 31 Research Policy 291-302, F. Malerba, "Sectoral Systems of Innovation and Production" (2002) 31 Research Policy 247-264, J. Fagerberg et al. (eds.), *The Oxford Handbook of Innovation* (Oxford: OUP, 2006), C. Lyall, "Changing Boundaries: The Role of Policy Networks in the Multi-Level Governance of Science and Innovation in Scotland" (2007) 34 Science & Public Policy 3-14, and more.

[12] Here 'best science' means that science which achieves a balance between efficient development and production, socially utility, and public acceptability, all of which will be negotiated depending on the particular innovation .

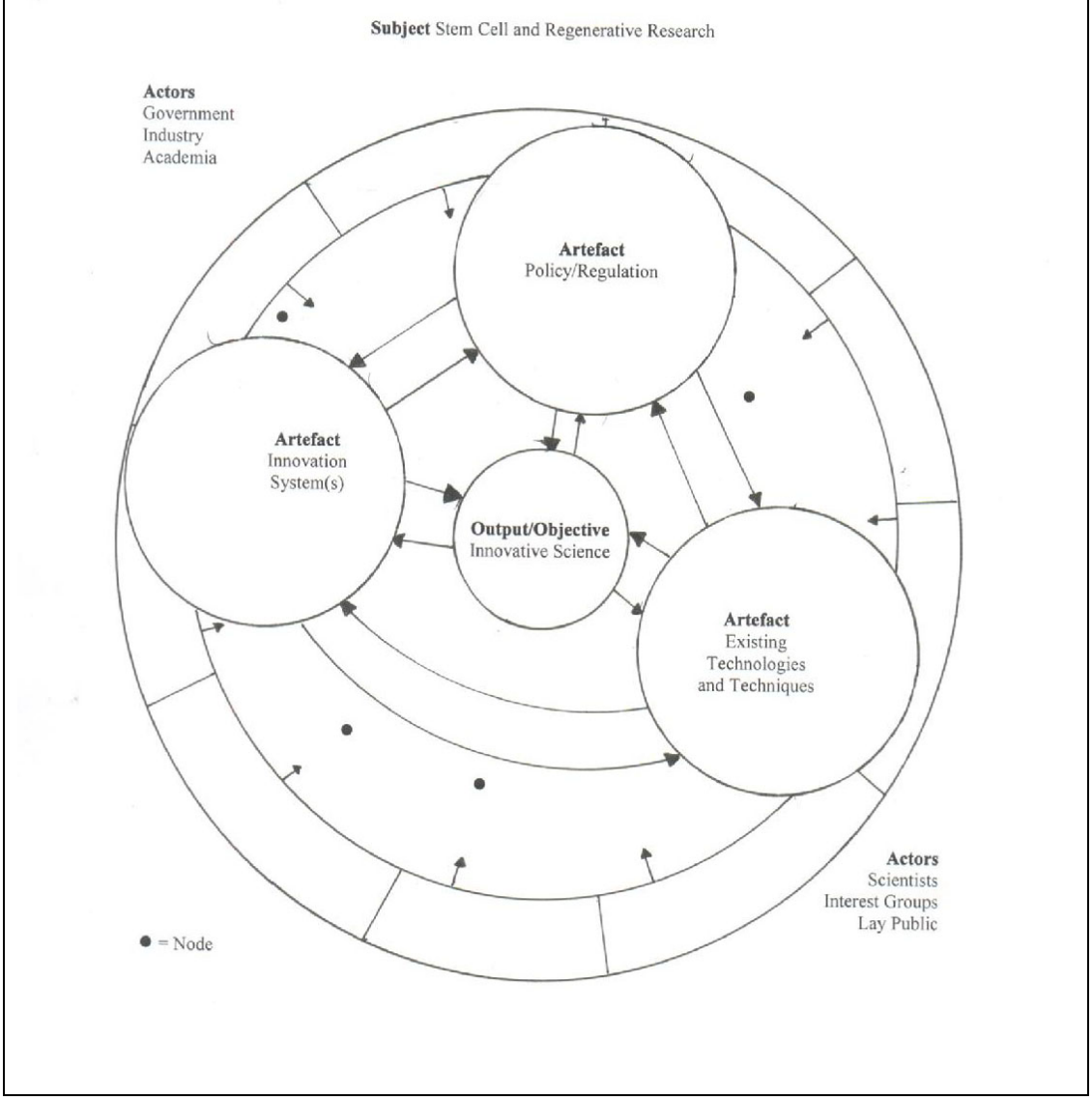
modify, and reconstitute themselves through a multi-directional interactive process that is facilitated by the nodes (but is by no means reliant on the nodes).

'Nodes' are notional intersections at which actors and artefacts come together to discuss, assess and perhaps adjust or correct the environment; these intersections may be geographic or temporal, institutional and ongoing, or intermittent or ad hoc. They serve as opportunities for actors to (re)shape the environment or constituent elements thereof in a proactive and productive way.

The similarities of the above model to a living cell are apparent, and appropriately so, for, like a cell, a healthy social/science environment is a living, thriving thing which must be nourished. Generally, one can imagine the following: the specific subject – in this case stem cell and regenerative science – is like a cell membrane, forming a thin, porous conceptual layer which encircles the social/science environment; actors, like the larger organism, might be seen to encase the membrane/subject, injecting and receiving information and thereby helping to shape both the subject and the environment; artefacts are like endoplasmic reticulum, contributing directly and indirectly to the primary output of the environment – bioscience; nodes are like mitochondria, generating the energy necessary to sustain or enhance the greater environment. Represented diagrammatically, a healthy environment might look as depicted in Diagram 1.[13]

[13] Though an argument can be made that the boundaries between the Artefacts themselves and between the Artefacts and the Output should be closer and more blurred. As previous scholarship has suggested, the separation between science and politics, for example, as distinct spheres of activity is not defensible. Science shapes politics – offering issues, influencing debates, impacting on careers – and science is shaped by political agendas and values. In short, knowledge in different walks of life develop together and influence each other. As such, one could argue that the environment is not quite as 'clean' as suggested, but the Diagram is appropriate insofar as it highlights the mutual interactions and major architectural elements.

Diagram 1
Model Bioscience Environment



Importantly, each artefact within the environment should be optimised if innovation opportunities are to be maximised (though weaknesses in one may be compensated for by aspects of the others). In order to optimise each artefact, interested actors must be given action space, that is the physical, temporal and cognitive space to reflect on, discuss, and influence the structures, so that the best combination of structure strengths, shapes and roles can be found. In short, communication and action space must exist not only at the nodes but within the artefacts themselves. The fact is that the nodes, while dynamic and energy-giving, might not be integrated into the governance structure. But the artefacts require some permanent space which offers opportunities for ongoing engagement so that confrontation can be transformed into collaboration and the environment itself can be influenced toward positive ends. Ultimately, each structure must afford interested actors space to critically assess the role and functioning of the structure itself, and to reform the structure and therefore the whole environment more generally, the primary aim being to improve science and, through science, society.

The question of whether the social/science environment is operating optimally – and therefore generating good science and scientific innovation (and perhaps also governance innovation) – is complex, requiring evidence from a range of actors and having reference to the policy objectives for the science in question. For present purposes, the question is: Based on the evidence available, to what extent does the Argentine environment reflect this notional model?

II. THE ARGENTINE CONTEXT: EVIDENCE AND THE SOCIAL/SCIENCE ENVIRONMENT

At the outset, it might be conceded that there will be very few jurisdictions which meet the ideal social/science environment, either from an architectural perspective or from an outcome perspective (ie: consistently generating the best science in the most efficient manner). Having said that, the evidence generated in the GET: Social Values Project, combined with scholarship on the Argentine science setting,[14] suggests that the Argentine social/science environment (in the bioscience context) is not particularly 'healthy'. Although select bioscience activity is internationally recognised and competitive,[15] and although Argentina's reproductive medicine services are second to none, we might suspect that the environment within which they work is sub-optimal with multiple interrelated and cascading blockages stemming from actor, artefact and node shortcomings.[16] The following section confirms this by considering some of the evidence in relation to each major element of the model environment

With respect to the relevant actors, there is evidence that:

- the range of empowered actors in the bioscience environment is narrow (ie: there is little diversity in active stakeholders);

- the representational possibilities of divergent actor viewpoints is uneven (ie: the formal dialogue is dominated by a few powerful institutions, most notably the Church);[17]

- the space within which actors can (publicly) operate is confined (ie: there are few opportunities for interested actors to network and to present a (unified) counter-point to some of the formal narratives); and

---

[14] See P. Kreimer and M. Lugones, supra, note 2, P. Kreimer, "Science and Politics in Latin America: The Old and the New Context in Argentina" (1996) 1 Science, Technology and Society 267-289, P. Kreimer and M. Lugones, "Pioneers and Victims: The Birth and Death of Argentina's First Molecular Biology Laboratory" (2003) 41 Minerva 47-69, F. Luna and A. Salles, "On Moral Incoherence and Hidden Battles: Stem Cell Research in Argentina" forthcoming in Developing World Bioethics, and more.

[15] In particular, one might take note of the activity being undertaken at the FLENI, Leloir Institute, Hospital Garahan and others.

[16] Note that the consequences of a persistently sub-optimal social/science environment can be inefficient use of, or diminishing availability of, science funds, decreasing quality of science and/or low levels of innovation, or weak public support of science and/or scientist migration to other jurisdictions, depending on what element of the environment is exerting negative impact.

[17] For more on the role of the Church, see F. Zegers-Hochschild, "Attitudes Towards Reproduction in Latin America: Teachings from the Use of Modern Reproductive Technologies" (1999) 5 Human Reproduction Update 21-25.

- there is general public support for science and scientists but also high science illiteracy and a willingness by portions of the public to self-censor actual values and ideas in the face of strong oppositional voices.

Specific responses in the GET: Social Values Project which reflect these findings are as follows:

> R5: [E]ach country should try to contribute to the debate … . I don't know the view of my country. I have no idea. I could guess, but I don't know. One group is very loud; that doesn't mean that they are many because they shout so loud. I would really like to know what my country's people would like to say about this subject [stem cell research].

> R11: … [P]eople here that make the law don't take care of scientists' opinions. They consult other people who are [involved] with political groups, not good groups [interested in] law, ethics [or] research. Here the influence of the Catholic Church is really, really important.

> R16: There is a wide gap between these: science, society and social conception of science. Of the research we did last year, 50% didn't understand 'cryopreservation' and 40% didn't understand 'gene therapy'; they collapse it into cloning and manipulation. … This is the reason why I consider that, in Argentina, people's perception of science is important but uninformed. … I am afraid that with stem cells it will be the same.

Another respondent (R15) stated that there had been a 'buzz' since US President Obama's statement on stem cell research funding, but that voices remain isolated because the rigid position of the Catholic Church forces people to be quite cautious about how they approach science discussions.

Ultimately, the relationship (and particular power dynamic) between certain central actors (eg: the church, media and political elites) serves as a bottleneck, blocking other actors from a more active role within the social/science environment. Thus, many actors who are otherwise interested in this setting are (or certainly feel) disempowered and unable to access in meaningful ways the spaces within which discussions might be undertaken and important decisions might be made.

In relation to the artefacts, two in particular were identified as deficient by respondents: the science policy/regulatory artefact and the existing technologies/techniques artefact. With respect to the former, most of those interviewed reported an inability to shape science legislation or to steer legislation and/or regulation in a rational and positive direction. For example:

> R11: Yes, [we need a law] but [a] rational [law]. I am afraid because in the past when the government [adopts] legislation about science—well not really good. …

> R15: It is very difficult to pass a logical law in [reproductive medicine] … which is a related field. … It is not only the Church, but also a lot of newspapers that are very controlling in the way they [present] abortion

and [similar] topics.

> R16: There is no regulation. We have discussed [fertility treatment regulation] since 1989 … but it hasn't been made into law because [of] the 'beginning of life' debate. It has made it impossible to regulate [this] work, for moral and religious reasons – I think it is more religious than moral.
>
> R20: To be honest, I am so sceptical of the possibility of regulating stem cell research that I totally understand why some people would much rather say, 'let's not start anything' … .

Another respondent (R5) shared the above frustration at the inability to shape good science regulation, but stated that scientists must form their own views about boundaries, and should (somehow) take part in any discussions which lead to a law.

With respect to the latter artefact – existing technologies and techniques – respondents articulated a lack of space to openly and intelligently explore the possibilities (for Argentina) of existing technologies and techniques. Technologies and practices are either consciously shuttered or hidden or, more often, simply not communicated to, or discussed within, the public (ie: science is performed behind closed doors and good science communication is not the norm). One respondent (R14) stated that scientists are not comfortable with announcing their research or their findings publicly because of feared reactions based on misunderstandings of science, and the respondent analogised this silence – this aversion to confrontation – to that experienced around the issue of divorce, an issue which bubbled below the surface for many decades until it exploded in the 1960s. One member of the Advisory Commission on Regenerative Medicine and Cellular Therapies stated that they tried to encourage an open debate on stem cell research in 2007/08, but many of the key actors were reluctant to do so because of concerns about negative attention.[18] Such an atmosphere, which might be characterised as defensive and oppressive, is detrimental to science and scientists themselves, and makes it impossible to deploy existing technologies to their maximum benefit.[19]

With respect to nodes, there have been and remain very few dynamic intersections of communication and creation. The Argentine MOST (and its predecessor, the Science and Technology Agency) sponsored two international policy conferences, one in 2007,[20] and one in 2008.[21] Both of these were ad hoc, as was a subsequent interactive workshop co-hosted by the Argentine Advisory Commission

---

[18] This member was not a respondent in the GET: Social Values Project but a member with whom the author had direct and ongoing communication.

[19] An example of uneven (and therefore unjust) deployment of existing technologies and techniques in Argentina is the deployment and availability of safe abortion practices. Cutting edge technologies and techniques are available, and are sourced by some, but are unavailable to the majority of people, primarily the poor, because abortion is still illegal in Argentina.

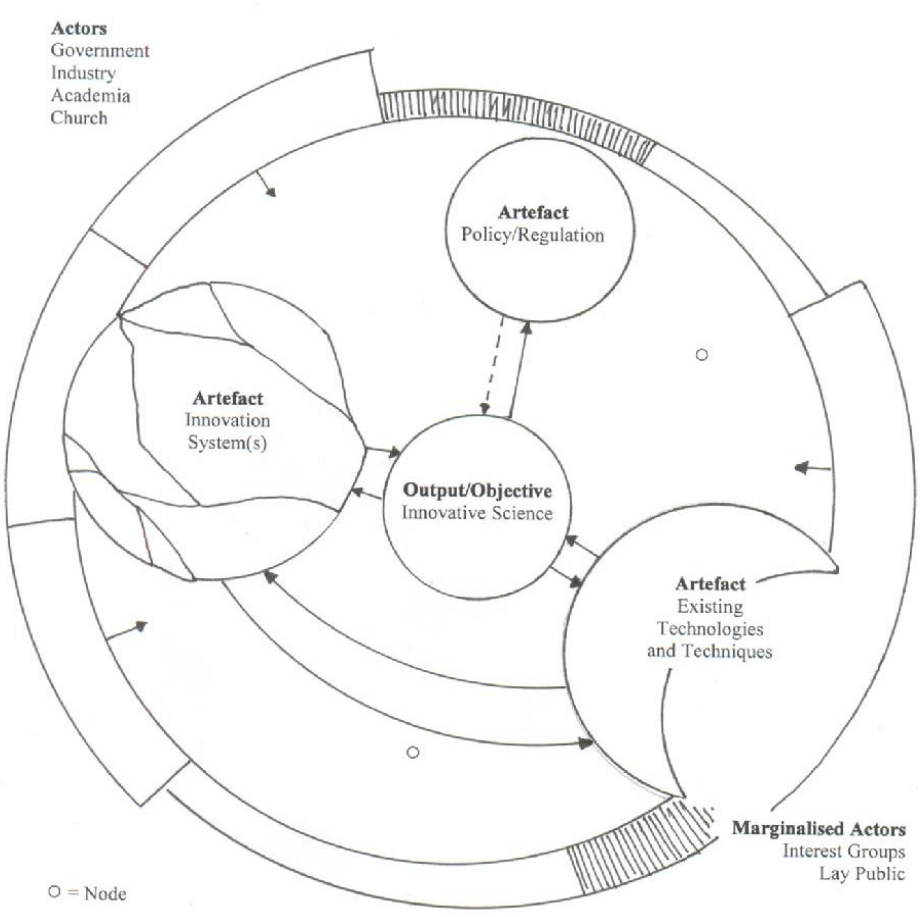
[20] Argentine Science and Technology Agency, "Regulation of Clinical Research Involving Stem Cells", 29-30 November 2007, Buenos Aires. For a report on this, see S. Harmon, G. Laurie and F. Arzuaga, "Regulation of Clinical Research Involving Stem Cells: Towards the Construction of a Regulatory Model for Argentina – Learning from the Experiences of the UK" (2008), available at http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/files/Report%20Nov%2007%20Stem%20Cell%20Workshop.pdf.

[21] Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies, "Second International Conference on the Regulation of Stem Cells and Human Tissue", 14 October 2008, Buenos Aires.

on Regenerative Medicine and Cellular Therapies and the GET: Social Values Project., which workshop was attended by some 40 invited participants.[22] In the latter case, participants lamented the absence of a more regularised means of coming together to discuss issues and to network in this field. One respondent (R16) reiterated this, stating that attendees at recent doctors' meetings indicated that they would like to work in this area (ie: in stem cell science) and they would like to have more contact with other organisations, including international institutions. The respondent also expressed a desire to discuss, work and learn in a more networked manner.

Based on all of the above, the Argentine stem cell and regenerative science environment might be diagrammatically represented as in Diagram 2.

Diagram 2
Argentine Bioscience Environment



[22] Argentine Advisory Commission on Regenerative Medicine and Cellular Therapies and GET: Social Values Project, "The Regenerative and Cellular Sciences: Values, Objectives and Issues for Implementation – An Interactive Workshop", 18 August 2009, Buenos Aires. For a report on this, see S. Harmon, "Regenerative Medicine Governance: Report of the Workshop on Governance Research Using Human Embryonic Tissue" (2009) 6:3 SCRIPTed 729-740.

Note that certain actors, most notably the lay public and patient groups, are thin/weak or missing (or blacked out from a communications point of view). Aside from the policy element, the policy/regulatory artefact is undernourished. There is almost no relevant existing legislation/regulation,[23] and the discursive space is largely closed down by powerful actors antagonistic to bioscience. The existing technologies artefact is partially concealed through science community silence and a relatively low level of science literacy, which means that technologies which are already being used (albeit unevenly) are not having the shaping effect on the environment that they might otherwise have. Although this was not addressed directly in the responses, the innovation systems artefact is not ideal (and is therefore represented as fragmented).[24] Finally, available nodes of communication and dynamism are few and are not yet well entrenched. Such then is the general social/science environment in Argentina; a sub-optimal environment the shortcomings of which include an inability to measure or cope with plurality as it relates to science trajectories or means of governing same, facts which are mostly apparent to many of the respondents in the GET: Social Values Project.[25]

Is there capacity and a will to improve the social/science environment in Argentina? Based on observed expertise and interview responses, the answer is clearly 'yes', and there are already some positive signs. For example, the National Institute for Organ Donation and Transplantation (INCUCAI) is becoming a useful conduit of scientific information and technical guidance for (an admittedly narrow range of) interested actors, a fact suggested by several respondents. More importantly, the MOST is evolving as an important site of information, action and motivation, as is the Advisory Commission on Regenerative Medicine and Cellular Therapies, which serves an important reflective or evaluative function. The work of these bodies since 2007 has made at least one element of the first artefact – science and funding policy and science legislation/regulation – quite robust and internationally engaged, and this largely as a result of the efforts of the new Minister of Science, Líno Barañao,[26] but even this space has been opportunistic and largely limited to science and policy elites.

However, as is perhaps clear, the scope of the task facing the MOST and other interested stakeholders is substantial. The remainder of the paper focuses on one element of the undertaking: legal reform (or action) within the policy/regulatory

---

[23] Both the Prohibition on Human Cloning Research, Presidential Decree No. 200/1997 and the *Transplantation Act 2007* are only peripherally relevant to this setting.

[24] For a critique of the innovation system artefact, see D. Chudnovsky, "Science and Technology Policy and the National Innovation System in Argentina" (1999) 67 CEPAL Review 157-176, C. Correa, "Argentina's National Innovation System" (1998) 15 International J Technology Management 721-760, K. Thorn, "Science, Technology and Innovation in Argentina" (2005), available at http://siteresources.worldbank.org/INTARGENTINA/Resources/ScienceTechnologyandInnovationinArgentina.pdf [accessed 22 February 2010], C. Morel et al., "Health innovation Networks to Help Developing Countries Address Neglected Diseases" (2005) 309 Science 401-403, and more.

[25] Put very succinctly, the interaction in Argentina of science, politics and society, the latter which is heavily and, from a rationalist's point of view, negatively influenced by the church, is not an ideal recipe for supporting (cutting edge) science and channelling it towards socially approved and useful purposes. The theoretical characterisations here are helpful for discussing their interaction and mutual reliance and for singling out aspects of an otherwise sometimes murky Argentine setting so that they can be considered in more manageable portions and thereby more carefully scrutinised.

[26] Several respondents singled out Minister Barañao as being a central figure, noting his particular experience and qualities as being important to this moment for science in Argentina.

artefact.

III. THE REGULATORY ARTEFACT: COPING WITH PLURALITY

Action and actor space at one artefact can be very important not only for the development of that artefact (and its outputs) but also for the overall social/science environment. More specifically, it has been suggested that action within and by the policy and regulatory artefact is vitally important to the science environment and to the beneficent potential of science:

> In democratic societies, technological development and application operates, so to speak, with a social licence – a licence which itself is subject to the overriding restraints of respect for human rights and human dignity. Accordingly, it falls to politicians and regulators, and ultimately to the law, to set the limits of technological innovation, to coordinate the assessment and management of risk, to design procedures for public participation, and to set the terms of compensatory responsibility. … [I]t also falls to the regulators and to the law to establish a governance environment that is supportive of desirable technological innovation and that ensures that benefits are fairly shared.[27]

In short, the convergence of diverse and novel technologies and their rapid penetration into the lived human experience, demands governmental action.

The empirical evidence generated by the GET: Social Values Project suggests that Argentine stakeholders – at least those interviewed – desire to have some boundaries articulated for bioscience, particularly that in the medical setting. Known boundaries, it was felt, would have at least two salutary effects. First, they would limit scientists by making clear what ends and/or methods are deemed to be (in)appropriate after existing methods and trajectories had been considered rationally (ie: it would reduce the possibilities of mavericks damaging the science/research reputation and agenda).[28] Second, they would empower scientists in a positive way by assuring them that all of their activities within that articulated sphere are defensible and need not be sheltered from public scrutiny (ie: it would encourage the unveiling of science without putting scientists on the defensive).

However, although almost all respondents felt that *government* boundary-setting (in particular) would be valuable, there was no consensus on how that boundary-setting might be achieved, and they did not all agree that formal regulation was essential. In this regard, opinions fell broadly into four camps:

- Camp 1 – No Legislation: It is too early for legislation in the stem cell setting (R7). Alternatively, legislation ought to be avoided because the tendency in Argentina is to ban and pass bad laws (R16). It might be better for this area to first be quietly overseen by a regulatory committee under the Ministry of Science or Health so some oversight and advice can be offered as the field develops, and any furore is avoided (R21).

---

[27] R. Brownsword and H. Somsen, "Before We Fast Forward – A Forum for Debate" (2009) 1 Law, Innovation & Technology 1-73, at 2.

[28] Returning to the social/science environment and the cell metaphor, unchecked science can easily go out of control and/or lose social utility, and might be seen as cancer.

- Camp 2 – Narrow Legislation: A stem cell-specific law is important because of the socially important issues thrown up by this research (R5, R10, R11, R14, R17, R19).

- Camp 3 – General Research Legislation: Stem cell practices and issues are shared with other research and medical practices and techniques so a general medical research law is more useful, under which technique-specific regulations might be drafted by the executive on an as-needed basis (R1, R4, R6, R8, R18).

- Camp 4 – General Medical Legislation: It is much more important to regulate the clinical setting than basic research; the safety of the patient is the most important element currently missing from the Argentine biomedical regulatory setting so it would be better to have a medical law (R3, R12, R15).

In short, and potentially compounding the confusion and dissatisfaction caused by the existing legislative and regulatory silence from the policy/legislation artefact, there was a plurality of opinions as to how this artefact (or bodies within it) should respond and shape itself with respect to science boundary-setting, and there was a scepticism as to whether the artefact could shake itself into action and set a course that engaged with this plurality (and other pluralities that might arise).

Given this plurality (on both the role of law and the shape/nature of publicly set boundary-setting for science) – a plurality which we might assume will be reproduced across society[29] – it remains to be determined how Argentine policymakers might respond. How might these very diverse (indeed contradictory) opinions be taken into account and (at least some of them) be put into action?[30] That is a big question for another time, and one dependent on a broader base of evidence than presently exists, but the outlook is not wildly encouraging. Some preliminary observations supported by the evidence are as follows:

- The present manifestation of the broad Argentine social/scientific environment, with its uneven access to voice and its few nodes for open public debate, seems ill-suited to exploring a plurality of science and boundary opinions in a constructive manner, and less suited to encouraging a negotiated narrowing of options such that action which is generally supported can be taken.

- Similarly, the potential of the policy/regulatory artefact to address a plurality of opinion in relation to either science boundaries or, more importantly,

[29] Though we should be cautious about extrapolating too much from respondent areas of agreement (eg: that science is beneficial and should be facilitated) and disagreement (eg: on legal responses), it is reasonable to assume that inclusion of a wider range of stakeholders (eg: interested segments of the public) will result in even greater plurality, not only on the legal element of the policy/regulatory artefact, but, perhaps more importantly, on the bioscience endeavour more generally, where we might expect some very deep divisions on issues of whether to pursue stem cell research, how to apply stem cell research outputs, and therefore how to regulate activity in this field.

[30] Given the plurality of opinion which we can assume exists in Argentina with respect to stem cell and regenerative science more generally, and given the problems that the current socio-legal context is creating, I would suggest that this particular plurality is indeed one that should be serious considered, actively engaged with, and eventually acted upon, one way or another.

methods for articulating and narrowing the plurality and then enforcing the boundaries ultimately agreed (ie: for shaping the artefact itself) seems seriously constrained due to a shortage of meaningful (and entrenched) policy discussion nodes and existing legislative fallowness.

- The possibility of the best placed and best suited actors in the subject environment (eg: the MOST and Ministry of Health) adopting a pragmatic but explicit (as opposed to pragmatic but veiled or partially hidden) course which legally entrenches bioscience innovation facilitation seems remote.[31]

Argentina might do well to look at what other jurisdictions have done when confronted with new technologies and social uncertainty. Some 30 years ago, the UK formed the Committee of Inquiry into Human Fertilisation and Embryology, which reflected upon and undertook extensive public consultation about reproductive clinical medicine and related research, knowing full well that a central question was the value to be given to human life and how the law should respond.[32] On the issue of plurality, (then) Dame Mary Warnock reported that the Committee encountered very diverse and strongly held opinions and understood that it would be impossible to satisfy all interested parties.[33] As such, a majority of the Committee settled on a compromise between sacralisation and instrumentalisation of the embryo, concluding that the human embryo had a "special status" entitling it to "some protection in law", and it advanced the view that, while the law must not outrage the feelings of too many people, it could not possibly reflect the feelings of them all.[34]

Of course, while it can be useful to explore successful policy practices, transplanting them from one jurisdiction to another is not necessarily the answer, especially where the cultural affinity of the receiving jurisdiction for the practice might be assumed be weak. Even if the Argentine appetite is weak for a lightning-rod body seeking public evidence and offering guidance, philosophical and legal, one gets the sense that Argentina's new MOST *is* open to ideas for improving both the actor space within the policy/regulation artefact as well as the general environment. Having said that, it seems unlikely that Argentine policymakers will, at this stage, take such a bold step as to, on the one hand, publicly acknowledge the (presumed) plurality of opinion on stem cell and regenerative science and the multiple courses open to it from a governance point of view (ie: the plurality of pluralities), and, on the other hand, explicitly define a course for acceptable uses of human tissue (including embryos) in stem cell and regenerative science. The existing social/science

---

[31] A key assumption being made here – and in developed country legal circles more generally – is that the policy/regulatory artefact should encourage and facilitate science innovation: see R. Brownsword and H. Somsen, supra, note 27, and S. Harmon, "Ambition and Ambivalence: Encouraging a 'Techno-Science Culture' in Argentina Through Engagement and Regulatory Reform" submitted.

[32] Established in July 1982, the Warnock Committee had the remit of: considering recent and potential developments in medicine and science related to human fertilisation and embryology; considering what policies and safeguards should be applied, including considering the social, ethical and legal implications of these developments; and making recommendations with a view toward legislation. The Committee contained seven doctors/researchers, three lawyers, two social workers, a theologian, a health administrator and an entrepreneur. It heard some 21 oral representations, considered evidence from hundreds of interested individuals and organisations, and received 695 letters and submissions from the public.

[33] M Warnock, *A Question of Life: The Warnock Report on Human Fertilisation and Embryology* (Oxford: Basil Blackwell, 1985) at 1.

[34] Ibid, at xvi and 63.

environment, which is heavily influenced by the dominant features of the broader socio-cultural-political environment, makes this a politically costly undertaking, and one potentially damaging to the interests of science protagonists.

That being said, there are recent Latin American examples of such bold moves being taken. Here the experience of Brazil, a similarly Catholic country, might be instructive. In March 2005, after years of campaigning by researchers and patient groups, the Brazilian Congress passed (by a vote of 352-60) the *Biosafety Law*.[35] Article 5 of that law allows the use of human embryos produced by IVF, if:

1. the embryos have been frozen for more than three years;
2. the embryos would be unlikely to survive if transferred to a woman;[36]
3. the progenitors give consent; and
4. they will not be used for therapeutic cloning.

In May 2005, the then Attorney General filed a Direct Unconstitutionality Claim,[37] alleging that the constitution stipulates that life occurs at the moment of conception and Article 5 therefore contradicts the constitutional principle of the inviolability of life. In April 2007, after some delay, the Brazilian Supreme Court held public hearings (for the first time in its history) during which it heard testimony from a range of experts. On 29 May 2008, the 11-member Court ruled, by a vote of 6-5, that Article 5 was constitutional. Throughout this period (pre-2005 to 2008), stem cell research suffered some uncertainty in Brazil (and stem cell projects had great difficulty finding funding),[38] but by October 2008 the first Brazilian stem cell line had been announced.[39] Also during this period, as a direct result of the legislative action, Brazil experienced intense information exchange and debate:

> The hearings at the Supreme Court demonstrated a democratic aspect of Brazilian society. Rarely has Brazilian society discussed any aspect of science or public health with such an intensity. Rarely have so many well-informed people expressed an opinion about a subject with legal, religious and scientific implications. Never before have Brazilian media realised such a wide coverage of science communication in a short period of time.[40]

Confirming scholarship in this arena,[41] this Brazilian adventure demonstrates the central role of the mass media in the policymaking arena – as attention-influencer, issue-definer, symbol-creator, and opinion-shaper. Indeed, it has been reported that the media's explanations were essential to the approval of the law.[42] Moreover, and

---

35 Law No. 11,105, 24 March 2005.

36 This non-viability condition was defined in Decree No. 5,591, 22 November 2005, as those embryos with proven genetic alterations that prevent development due to lack of cleavage.

37 Ação Directa de Inconstitucionalidade 3,510. The subsequent Attorney General filed a supporting brief with the Supreme Court.

38 M. Leite, "Stem Cell Research in Brazil: A Difficult Launch" (2006) 124 Cell 1107-1109.

39 D. Diniz & D. Avelino, "International Perspective on Embryonic Stem Cell Research" (2009) 43 Rev Saúde Pública 541-547.

40 C. Jurberg et al., "Embryonic Stem Cell: A Climax in the Reign of the Brazilian Media" (2009) 18 Public Understanding of Science 719-729, at 727.

41 See M. Nesbit & B. Lewenstein, "Biotechnology and the American Media: The Policy Process and the Elite Press, 1970-1999" (2002) 23 Science Communication 359-391.

42 C. Jurberg et al., supra, note 40.

very importantly, while it presented evidence on both sides of the debates, it did not bow to religious pressures but rather, at least in its selection of letters to be published and settings from which to broadcast, it evinced a bias reflective of public opinion as polled shortly before the Supreme Court's decision.[43]

The Brazilian experience demonstrates that, even in Latin American jurisdictions where the conservative Catholic Church has significance political and social influence, there is scope to fundamentally alter a key artefact (the policy/regulation artefact and its outputs) and thereby reform the whole social/science environment, and to do so by making morally-pregnant bioscience debates public and taking proactive steps to facilitate biosciences through law. It also suggests that doing so will inevitably be difficult and socially disruptive, but not necessarily damaging to science institutions and pursuits. Of course, much will undoubtedly depend on (1) the relative strengths of leading protagonists (eg: political and policy leaders) and resisting institutions (eg: the Church), (2) the willingness of supporting institutions (eg: eminent science bodies and academic institutions) to strongly engage, and (3) the responsibility and fairness of the media, which is generally recognised as a critical actor (ie: it must be prepared to reflect widely held social values for which there is some empirical base). One of the benefits of country-based studies like the GET: Social Values Project is to begin to provide that evidence base.[44]

In the absence of systemic or overt reform in Argentina, at least in the short term, one wonders whether the regulation of stem cell and regenerative science might best be achieved 'through the back door', as outlined by R21 in Camp 1 above. The approach suggested is not exactly 'status quo' because it envisions the formation of a specialised committee that advises scientists and reviews protocols put to it; it would be more proscriptive than the existing Advisory Commission on Regenerative Medicine and Cellular Therapies, which advises primarily upward, not outward. Such a body would probably be welcomed by the science community and pro-science publics insofar as it is flexible and helps to gradually develop regulatory capacity while building science momentum.

On the negative side, such an approach would inevitably be characterised by a distinct lack of clarity around boundaries and limits on acceptable behaviour, and by weak oversight and enforcement (ie: it would permit malfeasance and leave both it and misfeasance largely unpunished). Additionally, scientists who feel more secure undertaking their work quietly and anonymously would not be encouraged to open themselves and their work to public scrutiny any more than at present. Finally, it

---

[43] A January 2008 survey of Public Opinion Research Institute of Brazil (IBOPE) demonstrated that 75% of a 1,863 person sample (all between the ages of 16 and 70, and 1,230 of whom claimed Catholic membership) were in favour of embryonic stem cell research. A television poll reported that 66.7% of respondents were in favour of the use of embryonic stem cells, and letters to *O Globo*, a widely circulated newspaper, indicated a 64.7% favourable rate for stem cell research: C. Jurberg et al., ibid.

[44] The value of country-based studies has been noted by such luminaries as Sheila Jasanoff: see S. Jasanoff, "Controlling Biotechnology: Science, Democracy and 'Civic Epistemology' – Review Symposium" (2008) 17 Metascience 177-198. While acknowledging the importance of international institutions and "global socio-technical imaginaries spawned around biotechnology", she rightly asserts that politics, including science and technology politics, are local. If one wishes to influence sci-tech trajectories or boundaries, one engages national institutions. Thus, while international values and principles and international discourses are critical, possibilities for action are often (sometimes exclusively) national. This makes country studies (and comparative country studies) valuable, often beyond the subject country, and this is certainly the case for Latin American countries. While they are by no means homogenous, they share a lot of socio-economic and cultural features, making one relevant to another.

would fail to address the hypocrisy lamented so strongly:

> R13 (Translator): He is saying that we of course have the capacity [to have a debate on stem cell research]. We are sincere but there is hypocrisy. We have a tremendous struggle to manage every day … so starting to make the circle of information increase [is important].

Similarly, R15 expressed a need for more honesty in science settings; currently people say one thing but do another, or do something and say nothing at all, a hypocrisy which is perpetrated within the legislative, the scientific, and the public settings.[45]

The bottom line remains that most respondents are desirous of, and prepared for, something to happen in the Argentine policy/regulation artefact, and they generally hope that it is rational and sensitive to social and science needs, even if they diverge somewhat on what they feel is the best way forward from a policy or legislative point of view.

CONCLUSION

I have argued that the best science is developed at the nexus of three interacting and co-producing artefacts within a more diffuse but positive social/science environment which includes publicly acknowledged science/knowledge needs and desires. Where these artefacts are open, dynamic and relatively harmonious, the best science is most likely produced. Drawing on a variety of sources, including empirical evidence, I have also argued that the Argentine model is not at all optimal: its actors are too unevenly empowered; its artefacts are either underdeveloped (the policy/regulatory artefact), or veiled (existing technologies), or fragmented (the innovation systems artefact); and its nodes are ad hoc and weakly action-guiding. Finally, focussing on the science policy/regulation artefact and the actor space in relation thereto, I have argued that there is a plurality of opinions amongst elite stakeholders with respect to how best to proceed in relation to stem cell and regenerative science.

Through this undertaking, the reader will have (hopefully) gained a better understanding of the complexities of the social/science environment and of the encouragement of innovation therein, and, more centrally, of Argentina's position in comparison to the model environment, as well as of some of the key issues facing Argentina, one of the most important of which is plurality. Of course, exposing this plurality is important but insufficient. given the incapacity of the Argentine social/science environment and bioscience policy/legislation artefact to measure this plurality or to cope with it in a constructive manner, in part because of an absence of actor space therein.[46]

Having been put on notice that plurality (or a particular plurality) exists, it behooves actors (including Argentine policymakers and researchers interested in Argentina) to expand the evidence base, measure plurality more accurately, and respond to it practically and rationally. A next important step may be to solicit thoughtful value evidence from other important stakeholders such as Church and media representatives and publics, and then to ease cautiously into a more active public engagement programme sponsored by the MOST, the Ministry of Health, and

---

[45] See also the discussion in F. Luna & A. Salles, supra, note 14.

[46] Related to this, neither the credibility of science nor the aspirations of publics for science can be accurately gauged in Argentina

interested academic institutions.[47] The bottom line is that Argentina would do well to fashion a bioscience regulatory framework worthy of the scientists currently plying their trade in Argentina – they and the legacy they are fulfilling deserve no less.

It has been argued that political cultures (and we might say social/science environments) manifest in the routinized ways that knowledge is produced, disseminated, evaluated and deployed in society.[48] By creating the MOST, Argentina has begun to shift the boundaries of science and politics and thereby alter its political culture (and social/science environment). However, a positive and enduring reshaping, as demonstrated by Brazil (which is still consolidating after a major shift), requires courage and the participation of publics, particularly in a democracy where science is part of a nation-building project or national re-imagining.[49] As hinted at by recent evidence,[50] one *might* discover greater consensus than formal dialogues to date have suggested, and therefore greater scope to facilitate the scientific and regulatory work being pursued in Argentina.

---

47 The ultimate goal being to reform the science policy/legislation artefact and/or its primary relevant instruments, or both, thereby improving the relevant institutions, the broader artefact and, ultimately, scientific outputs and uptake.

48 S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (NJ: Princeton U Press, 2005).

49 This is certainly the case in Argentina, as it was in the UK and the US: see S. Jasanoff, ibid.

50 See L. Vaccarezza, C. Polino and M. Fazio, "Measuring Public Perception of Science in Ibero-America: The RICYT/OEI's Study and Argentina's National Survey" in B. Bonnmatí (ed.), *Scientific Knowledge and Cultural Diversity: PCST-8 Proceedings*, (Barcelona: Rubes Editorial, 2004) 436-443, and G. Stekolschik et al., "Does the Public Communication of Science Influence Scientific Vocation? Results of a National Survey", Public Understanding of Science, published online 13 July 2009 and available at http://pus.sagepub.com/cgi/rapidpdf/0963662509335458v1 [accessed 15 February 2010].